

JURISDICTION AND VENUE

4. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) in that the parties are citizens of different States and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

5. The Court has personal jurisdiction over Defendants under N.Y. C.P.L.R. §§ 301 and 302. Witham, on behalf of Paragon, contacted Altaire representatives in New York to propose a business relationship and traveled to New York to negotiate a written Agreement (the “Agreement”) between the parties.¹ The Agreement states, in part: “The parties to this Agreement agree that jurisdiction and venue of any action brought pursuant to this Agreement, to enforce the term hereof or otherwise with respect to the relationships between the parties created or extended pursuant hereto, shall properly lie in the Court(s) of the State of New York or the Court(s) of the United States having jurisdiction over Suffolk County, New York.” The Agreement further states: “The validity, construction and enforcement of, and the remedies under, this Agreement shall be governed in accordance with the laws of the State of New York.”

6. Paragon employees have since visited Altaire in New York on numerous occasions during the course of the relationship between the parties, and in relation to the Agreement.

7. Venue is proper in this District under 28 U.S.C. § 1391(b)(2), in that a substantial part of the events or omissions giving rise to the claims occurred in this District, and in accordance with the venue provisions referenced in paragraph 5.

¹ Agreement between Altaire Pharmaceuticals, Inc. and Paragon BioTeck, Inc. Because the Agreement contains confidential information, Plaintiff will seek to file the Agreement under seal, subject to this Court’s approval, and incorporate the Agreement into this Complaint by reference as Exhibit 1.

FACTUAL BACKGROUND

The Agreement

8. In 2011, Witham, Paragon's President and CEO, contacted Assad (Al) Sawaya, the President of Altaire, in New York and proposed a business relationship between Paragon and Altaire. Witham and Sawaya were acquainted through Witham's previous employer.

9. Specifically, Witham proposed that Paragon and Altaire work together to file New Drug Applications ("NDA"s) with the Food and Drug Administration ("FDA") for certain ophthalmic products, including a solution containing phenylephrine. Phenylephrine is a pupil-dilating agent commonly used by physicians and optometrists during eye examinations. The FDA has categorized phenylephrine as a medically necessary drug.

10. For many years before Witham contacted Altaire, Altaire had been manufacturing and selling its phenylephrine formulations in the marketplace. Altaire agreed to work with Paragon to submit NDAs to the FDA in part because in 2011, the FDA issued stricter guidelines regulating the marketing and selling of drugs unapproved by the FDA. Altaire believed that by working with Paragon to obtain FDA approval for its products, it would achieve greater protection and exclusivity in the marketplace with respect to those products.

11. After a period of negotiation, Paragon and Altaire entered into the Agreement on May 30, 2011.

12. The Agreement obligated Altaire to provide the Chemistry, Manufacturing, and Control ("CMC") sections for NDA filings that were to be submitted by Paragon on phenylephrine hydrochloride ophthalmic solution, 2.5% and 10% ("phenylephrine"), and on a second product (hereinafter referred to as "Product B"). Altaire also agreed to manufacture and

supply the products in the Agreement. All of the research, development, and drafting of the CMC sections for phenylephrine took place in New York, and all manufacturing of that product takes place in New York. Altaire maintains no other manufacturing site.

13. Pursuant to the Agreement, Altaire was to be the exclusive manufacturer and supplier of the products once Paragon obtained FDA approval to market the products. Paragon was to be the exclusive marketer and distributor of the products.

14. The Agreement contained a “Confidentiality/Non-disclosure” section which, in part, acknowledged that all of Altaire’s CMC materials and information disclosed pursuant to the Agreement was proprietary and confidential information, not to be disclosed to any third party without Altaire’s written consent.

15. The Agreement was signed by Al Sawaya for Altaire and Patrick Witham for Paragon.

16. Altaire provided the CMC section for phenylephrine as required by the Agreement, and Paragon’s phenylephrine solution was approved by the FDA on March 21, 2013.

Negotiations Regarding “Product B”

17. After the FDA approval of phenylephrine, Altaire contacted Paragon and offered to start the process for obtaining approval of Product B. Paragon, however, through Patrick Witham, informed Altaire that it was not certain whether it wanted to move forward with the approval process for Product B, despite its contractual obligation to prepare and submit the NDA applications for both phenylephrine and Product B. Witham then informed Altaire that Paragon wanted to pursue FDA approval of a third product, not Product B. For the next nine

months, Altaire took steps to prepare for an Abbreviated New Drug Application (“ANDA”) filing for the third product.

18. In early 2014, Paragon sent Altaire a draft amendment to the Agreement regarding the replacement of Product B with the third product. Altaire objected to portions of the draft. Negotiations regarding the draft amendment ensued, but the amendment was never signed or executed because Paragon never sent Altaire a revised amendment that reflected all of the changes that had been discussed by the parties. Without an executed amendment to the Agreement, Altaire had no basis for which to move forward with the new product, and Paragon never took steps to follow up with Altaire regarding its intent to complete an NDA or ANDA filing with the FDA for the third product or for any other “Product B” as contemplated in the Agreement.

Paragon’s Patent Application and Issuance

19. On June 12, 2013, Paragon’s attorney contacted Altaire and informed Altaire that Paragon wished to amend the Agreement between Altaire and Paragon to allow Paragon to use Altaire’s confidential information in connection with applying for and obtaining a patent for phenylephrine.

20. Altaire responded to Paragon by stating that the proposed amendment was not acceptable as Paragon had drafted it and that Altaire would not agree to amend the Agreement in the manner Paragon was suggesting. Altaire also reminded Paragon that it was prohibited from using or disclosing Altaire’s confidential information beyond the limited purpose of obtaining NDA approval, pursuant to the terms of the Agreement.

21. In the fall of 2013, without further discussion with Altaire, Paragon filed for and was subsequently issued a United States Patent No. 8,859,623 (the “’623 patent”), entitled “Methods and Compositions of Stable Phenylephrine Formulations.”

22. Upon Information and belief, Paragon used and disclosed Altaire’s confidential information without written consent, as defined by and in violation of the Agreement, in its submissions to the United States Patent and Trademark Office (“USPTO”) to obtain the ‘623 Patent.

23. While Altaire has performed its duties and fulfilled its obligations under the agreement, Paragon’s use of Altaire’s proprietary and confidential information to obtain a patent has materially damaged Altaire by allowing numerous parties access to Altaire’s proprietary and confidential information, expanding the market for phenylephrine production, enabling competitors to develop Altaire’s own product, and decreasing Altaire’s revenue and profits.

COUNT I
Breach of Contract

24. The preceding paragraphs of this Complaint are incorporated by reference as if set forth fully herein.

25. Altaire and Paragon entered into the Agreement on May 30, 2011.

26. The contract required Paragon to, in part:

- a. Serve as the exclusive marketer and distributor of the phenylephrine product.
- b. Refrain from using Altaire’s confidential and proprietary information for any purpose other than obtaining the NDA approvals referenced in the Agreement.
- c. Prepare and submit NDA applications in support of both the phenylephrine product and Product B.

27. Altaire performed its responsibilities under the Agreement by providing and bearing the costs for the CMC sections of Paragon's NDA filings for the phenylephrine product and manufacturing and supplying such product upon and since NDA approval. Altaire also began the process of providing the CMC section of the Product B NDA, but Paragon failed to follow through with its obligation to prepare the NDA for Product B.

28. Paragon breached the Agreement by, in part:

- a. Failing to comply with its obligations under the Agreement with respect to obtaining an NDA on a second product, thereby depriving Altaire of the benefits associated with manufacturing and selling that product under the Agreement.
- b. Disclosing Altaire's confidential and proprietary product information in its patent application and subsequent patent.

29. As a result of Paragon's breach of the Agreement, Altaire has suffered damage.

COUNT II
Misappropriation of Confidential and Proprietary Information

30. The preceding paragraphs of this Complaint are incorporated by reference as if set forth fully herein.

31. Altaire provided confidential and proprietary information to Paragon for the limited purpose of obtaining NDA approval.

32. Pursuant to the Agreement, Paragon explicitly agreed to use that confidential and proprietary information only for that limited purpose.

33. Paragon instead used that confidential and proprietary information to obtain a patent from the USPTO, in bad faith, and in conscious disregard of the Agreement between Paragon and Altaire.

34. As a result of Paragon's misappropriation of confidential and proprietary information, Altaire has suffered damage.

COUNT III
Unfair Competition

35. The preceding paragraphs of this Complaint are incorporated by reference as if set forth fully herein.

36. The confidential information Altaire provided to Paragon under the agreement constituted a commercial advantage.

37. Paragon misappropriated that commercial advantage by acting in bad faith by withholding material facts and information from Altaire regarding Paragon's efforts to obtain the '623 patent and the use of Altaire's confidential and proprietary information in the course of obtaining that patent.

38. As a result of Paragon's unfair competition, Altaire has suffered damage.

DEMAND FOR JURY TRIAL

39. Plaintiff demands a jury trial on all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests:

1. The Court enjoin Paragon from further breaching the Agreement for the remainder of the Agreement's term.
2. The Court enter judgment for and award damages in favor of Altaire for all economic, monetary, actual, consequential, and compensatory damages in an amount to be determined at trial, but in no event less than \$75,000.

3. Award punitive damages to the extent allowable by law.
4. Award attorneys' fees and costs of suit.
5. Award pre- and post-judgment interest to the extent allowable by law.
6. Grant such other and further relief as allowed by law.

Dated: April 28, 2015

Respectfully submitted,

By: /s/ Colleen Kilfoyle

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